UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

KAREN WONG, derivatively on behalf of CHEMBIO DIAGNOSTICS, INC., Plaintiff, vs. RICHARD L. EBERLY, GAIL S. PAGE, NEIL A. GOLDMAN, JAVAN ESFANDIARI, KATHERINE L. DAVIS, MARY LAKE POLAN, and JOHN G. POTTHOFF, Defendants, and CHEMBIO DIAGNOSTICS, INC., Nominal Defendant.	Case No.: 1:20-cv-04269 **DEMAND FOR JURY TRIAL**

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

INTRODUCTION

Plaintiff Karen Wong ("Plaintiff"), by Plaintiff's undersigned attorneys, derivatively and on behalf of Nominal Defendant Chembio Diagnostics, Inc. ("Chembio" or the "Company"), files this Verified Shareholder Derivative Complaint against Defendants Richard L. Eberly ("Eberly"), Gail S. Page ("Page"), Neil A. Goldman ("Goldman"), Javan Esfandiari ("Esfandiari"), Katherine L. Davis ("Davis"), Mary Lake Polan ("Polan"), and John G. Potthoff ("Potthoff") (collectively, the "Individual Defendants," and together with Chembio, the "Defendants") for breaches of their fiduciary duties as directors and/or officers of Chembio, unjust enrichment, and for violations of Section 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). As for Plaintiff's complaint against the Defendants, Plaintiff alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based

upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by the Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Chembio, legal filings, news reports, securities analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Chembio's directors and officers from March 12, 2020 through June 16, 2020, both dates inclusive (the "Relevant Period").

2. Chembio is a point-of-care diagnostics company that develops and commercializes patented technology platforms aimed at, among other things, detecting and diagnosing infectious diseases.

3. As is now a well-known fact, a novel virus and respiratory illness, designated as COVID-19, originated in China in late 2019. After beginning to rapidly sweep through the world's human population, the World Health Organization declared COVID-19 a pandemic on March 11, 2020. Shortly afterwards, on March 13, 2020, the United States declared a national emergency concerning the COVID-19 outbreak. In its swift and ongoing spread, not only has the virus resulted in millions of infections and hundreds of thousands of deaths to date, but it has also largely left the global economy and many national healthcare systems in disarray.

4. In attempting to contain, control, and prevent the mass transmission of COVID-19, and its devastating effects, world leaders, including U.S. federal and state government officials and public health officials, have implemented extraordinary policy measures such as sheltering-

in-place, quarantining, and social distancing measures. Within the United States, the development of reliable mass testing techniques for COVID-19 has heavily guided many lawmakers' strategies.

5. For state and federal government officials, possessing accurate methods of testing for COVID-19 has become a vitally important tool for reducing the spread of the virus. Accurate diagnostic and serological[1] tests that are readily accessible to the public provide much-needed data on where the most serious outbreaks of the virus occur, and offer insight into where medical and other resources should be allocated, and what public policy measures are appropriate or effective.[2]

6. In an effort to mitigate the virus's damage and to end this pandemic, U.S. officials have worked with many businesses, including life science, biotechnology, and pharmaceutical companies to develop COVID-19 tests, treatments, and vaccines. Although many corporate leaders have risen to this unique challenge, the Individual Defendants have failed to meet this moment in time with the professional aptitude, honesty, and integrity this historic undertaking requires.

7. Early in the COVID-19 pandemic, it appeared that Chembio was able to utilize its diagnostic testing experience and know-how to quickly develop an exceptionally accurate

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[1] *Serology Testing for COVID-19 at CDC*, CENTER FOR DISEASE CONTROL AND PREVENTION (May 23, 2020), https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html#:~:text=An%20antibody%20test%20looks%20for,immune%20response%20to%20the%20infection. (defining serology testing as antibody testing that "looks for the presence of antibodies, which are specific proteins made in response to infections. Antibodies are detected in the blood of people who are tested after infection; they show an immune response to the infection. Antibody test results are especially important for detecting previous infections in people who had few or no symptoms.").

[2] *See generally* Rob Stein, Carmel Wroth & Alyson Hurt, *U.S. Coronavirus Testing Still Falls Short. How's Your State Doing?*, NPR (May 7, 2020, 5:00 AM), https://www.npr.org/sections/health-shots/2020/05/07/851610771/u-s-coronavirus-testing-still-falls-short-hows-your-state-doing (explaining the importance of testing for COVID-19); Rob Stein, *As Coronavirus Surges, How Much Testing Does Your State Need to Subdue the Virus?*, NPR (June 30, 2020, 5:05 AM), https://www.npr.org/sections/health-shots/2020/06/30/883703403/as-coronavirus-surges-how-much-testing-does-your-state-need-to-subdue-the-virus (explaining the importance of testing for COVID-19).

serological test for COVID-19 that simultaneously produced speedy results. As a result, Chembio's COVID-19 antibody test was one of the first to an extremely competitive and time-sensitive market.

8. Specifically, according to the Company's quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2020 (the "2Q20 10-Q"), Chembio refocused its business strategy on the development and commercialization of its proprietary Dual Path Platform ("DPP") technology, invented by Defendant Esfandiari, for a rapid antibody test for COVID-19 in January 2020.

9. On March 12, 2020, Chembio published a press release titled "Chembio and LumiraDx Limited ("LumiraDx") Announce COVID-19 Strategic Partnership" (the "March 12 Press Release 1") announcing that the Company had entered into a strategic partnership with LumiraDx, a company purportedly focused on developing, manufacturing, and commercializing industry leading point-of-care diagnostic platforms, with the current goal, among other things, of developing a diagnostic test for the detection of the COVID-19 virus and IgM and IgG antibodies using its DPP. On this news, the price of Chembio's shares increased during after-hours trading from $3.10 per share at the close of trading on March 11, 2020, to $4.19 per share at market open on March 12, 2020.

10. By March 20, 2020, with regulatory approval still pending, customers had already begun to place orders to purchase the Company's rapid COVID-19 antibody test.

11. According to the 2Q20 10-Q and a Company press release published on April 15, 2020 titled "Chembio Diagnostics Receives Emergency Use Authorization for DPP COVID-19 System for IgG and IgM Antibodies" (the "April 15 Press Release"), on April 15, 2020, the U.S. Food and Drug Administration ("FDA") granted Chembio an Emergency Use Authorization ("EUA") for emergency use of its rapid COVID-19 antibody test in the United States. Also in

April 2020, Brazil's Agenica Nacional de Vigilancia Sanitaria ("ANVISA") granted regulatory approval for use of its rapid COVID-19 antibody test.

12. The 2Q20 10-Q also asserted that Chembio's COVID-19 antibody test obtained regulatory clearance from the European Union when it was issued a CE Marking on or about May 4, 2020, enabling its sale in the European community.

13. Thereafter, as explained in the 2Q20 10-Q, Stony Brook Medicine selected Chembio's rapid antibody test to help identify persons who have recovered from COVID-19 for use in an FDA-approved investigation to determine whether those persons' antibodies can help treat patients with an active COVID-19 infection.

14. Throughout the Relevant Period, Chembio published press releases and held conference calls in which the Individual Defendants explicitly claimed and continued to maintain that Chembio's rapid COVID-19 antibody tests were of high quality and were 100% accurate after 11 days following the onset of symptoms—assertions that helped the Company distinguish itself and establish a crucial competitive advantage over other life sciences companies in a new but increasingly saturated market.

15. Investors were largely convinced by the Individual Defendants' representations. During the Relevant Period, the price of Chembio's shares increased from a closing price of $3.10 per share on March 11, 2020—the day before the start of the Relevant Period—to a Relevant Period high of $15.54 per share on April 24, 2020, a staggering increase of more than 401%.

16. According to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2019 (the "2019 10-K"), the Company has incurred losses every year from 2014 through 2019.[3] In light of these circumstances, Chembio's ability to continue operating depended

[3] Moreover, as explained below in more detail, the Company admitted in its quarterly report on

on whether Chembio could secure and maintain FDA approval for its rapid COVID-19 antibody test.

17. Strapped for cash, during the Relevant Period, Chembio conducted a secondary public offering in May 2020 (the "May 2020 Offering") in order to raise funds the Company desperately needed to sustain its operations and continue the development and distribution of its rapid COVID-19 antibody test.

18. In prospectus supplements issued in connection with the May 2020 Offering, the Individual Defendants touted the Company's rapid DPP COVID-19 System, asserting that "[t]he accuracy of the DPP COVID-19 System after 11 days post the onset of symptoms is 100% for total antibodies." Additionally, the Individual Defendants flaunted the Company's overall prospects, representing that the Company acquired, among other regulatory approvals, an EUA from the FDA for its rapid COVID-19 antibody test.

19. In truth, as set forth in the FDA's June 16, 2020 letter addressed to the Company[4] (the "June 16 Letter"), the Company's rapid COVID-19 antibody test was far less effective than the Individual Defendants purported, as it produced a high false negative rate and high false positive rate. The June 16 Letter also indicated that the FDA had previously voiced these and related concerns to the Company on numerous occasions over the course of the Relevant Period. Given the Company's precarious financial position, the Individual Defendants were highly motivated to conceal any deficiencies in the rapid COVID-19 antibody test—and indeed, they neglected to disclose these and other flaws to the investing public.

Form 10-Q filed with the SEC on May 4, 2020 that the pandemic significantly affected its operating results and forced the Company to reallocate resources towards ramping up its COVID-19 antibody testing at the expense of continuing to develop testing for other infectious diseases.

[4] The FDA's June 16, 2020 letter was addressed to the Company, care of the Company's current Director of Research and Development, Regulatory Affairs, Louise M. Sigismondi, Ph.D.

20. In connection with the May 2020 Offering, the Individual Defendants offered and sold approximately 2,619,593 shares of Chembio common stock, priced at $11.75 per share. Total gross proceeds from the offering equaled nearly $30.8 million.

21. The truth emerged after the market closed on June 16, 2020, when the FDA issued a press release titled "Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chembio Antibody Test" (the "June 16 FDA Press Release") announcing that it had revoked Chembio's EUA for the DPP COVID-19 System. Among other things, the FDA's press release stated that Chembio's test "generates a higher than expected rate of false results and higher than that reflected in the authorized labeling for the device," and that "it is not reasonable to believe that the test may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the test outweigh the known and potential risks of the test."

22. The next day, on June 17, 2020, the Company filed a current report on Form 8-K with the SEC (the "June 17 8-K") acknowledging that the FDA had revoked Chembio's EUA for its rapid COVID-19 antibody test, effectively barring the Company from distributing the tests due to "performance concerns regarding the sensitivity and specificity." The Company would subsequently begin working on a modified version of its COVID-19 antibody test.

23. As a result, on June 17, 2020, the Company's stock price plummeted from its closing price on June 16, 2020 of $9.93 per share. The Company's stock hit an intra-day low of $3.51 per share, a drop greater than 64%, before settling at $3.89 per share at the close of trading on June 17, 2020, more than a 60% decrease, on an uncommonly massive trading volume of nearly 27 million shares.

24. In fact, Chembio's rapid COVID-19 antibody test was materially less than 100% accurate after 11 days post the onset of symptoms, since even a seemingly minor inconsistency in

precision can have highly significant ramifications on the usefulness of a diagnostic testing product.[5]

25. Typically, the difference between a 99.5% and 100% accuracy rate is virtually nonexistent. However, in testing of infectious diseases, the mere 0.5% difference can have a substantial effect on whether policymakers can rely on the results of the test to formulate plans and endorse directives to reduce the spread of the virus.

26. For instance, if approximately 5% of individuals showing symptoms of the virus test positive for COVID-19 antibodies, then only about 50 symptomatic people test positive per 1,000 tests administered. If a COVID-19 antibody test has a specificity of 99.5%, five false positives would follow, i.e. five people would test positive for the virus but not actually have had the virus. Therefore, approximately 10% of the individuals who tested positive, i.e. five people out of fifty, would not, in fact, have had COVID-19. Accordingly, even an antibody test with a seemingly high specificity may fail to successfully and adequately guide public health policy vis-à-vis testing and contact tracing.

27. Here, Chembio's test results appear to have fared poorer than the numbers reflected in the foregoing hypothetical. According to the FDA's June 16 Letter, data generated from independent evaluations of the Company's rapid COVID-19 antibody test performed in or about April and May 2020 by the Department of Health and Human Services ("HHS"), National Institutes of Health ("NIH"), and National Cancer Institute ("NCI") (collectively, the "Independent

[5] As explained in greater detail below, tests intended for widespread public use must be decidedly exact in order to provide significant value given that an accuracy rate even marginally less than 100% can render a test futile in practice. For instance, if a test has a 98% "sensitivity" rate (which measures how well a test identifies true positives) and a 98% "specificity" rate (which measures how well a test identifies true negatives), the upshot is that approximately one-third of the tests will yield a false positive result. Accordingly, holding tests to a near perfect standard in clinical trials is vital to ensuring a reliable and safe product is delivered to the public.

Evaluators"), demonstrated poor performance with respect to its sensitivity and specificity. Moreover, the FDA notified the Company by emails throughout April and May 2020 of its concerns regarding the Chembio antibody test's deficient results observed by the Independent Evaluators.

28. Consequently, in stark contrast to Defendant Eberly's and the rest of the Individual Defendants' claims, it appears that Chembio's tests are not only less than 100% accurate after 11 days post the onset of symptoms, but are far less than even 99.5% accurate, and are hardly high-quality tests.

29. During the Relevant Period, the investing public was under a false impression of the Company's business, operations, and financial success.

30. During the Relevant Period, the Individual Defendants, in breach of their fiduciary duties owed to Chembio, willfully or recklessly made and/or caused the Company to make false and misleading statements and omissions. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (1) the Company's rapid COVID-19 antibody tests were less than 100% accurate after 11 days post the onset of symptoms; (2) the Company's rapid COVID-19 antibody tests generated a higher than expected rate of false results and higher than that reflected in the authorized labeling for the testing device; (3) the FDA had expressed grave and material performance concerns regarding the sensitivity and specificity of Chembio's rapid COVID-19 antibody test prior to revocation of the EUA on June 16, 2020; (4) accordingly, it was not reasonable to believe that the Company's rapid COVID-19 antibody tests may be effective in detecting COVID-19 resultant antibodies and, therefore, there was a material risk to public health from the poor performance and high rate of false test results; (5) the

commercial viability of the Company was overstated in light of the true accuracy and efficacy of the Company's COVID-19 tests; and (6) the Company failed to maintain internal controls. As a result of the foregoing, the Individual Defendants' statements about the Company's business, operations and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

31. The Individual Defendants failed to correct and caused the Company to fail to correct these false and misleading statements and omissions of material fact, rendering them personally liable to the Company for breaching their fiduciary duties.

32. Also in breach of their fiduciary duties owed to Chembio, the Individual Defendants failed to maintain internal controls.

33. The Individual Defendants' breaches of fiduciary duty and other misconduct have subjected the Company, its President and Chief Executive Officer ("CEO"), and its former interim CEO to four federal securities fraud class action lawsuits pending in the United States District Court for the Eastern District of New York (the "Securities Class Actions")—one of which also names the Company's Chief Financial Officer ("CFO")—the need to undertake internal investigations, and losses due to the unjust enrichment of the Individual Defendants who benefitted from the wrongdoing alleged herein, and will likely cost the Company going forward millions of dollars.

34. The Company has been substantially damaged as a result of the Individual Defendants' knowing or highly reckless breaches of fiduciary duty and other misconduct.

35. In light of the foregoing breaches of fiduciary duty engaged in by the Individual Defendants, the majority of whom are the Company's current directors, of the collective engagement in fraud and misconduct by the Company's directors, of the substantial likelihood of

the CEO's liability in the Securities Class Actions and this derivative action, and of their not being disinterested or independent directors, a majority of the Board of Directors (the "Board") cannot consider a demand to commence litigation against themselves on behalf of the Company with the requisite level of disinterestedness and independence.

JURISDICTION AND VENUE

36. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1) and Rule 14a-9 of the Exchange Act, 17 C.F.R. § 240.14a-9.

37. This Court also has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims also raise a federal question pertaining to the claims based on violations of the Exchange Act made in the Securities Class Actions.

38. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

39. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

40. Venue is proper in this District because a substantial portion of the transactions and wrongs complained of herein occurred in this District, and the Defendants have received substantial compensation in this District by engaging in numerous activities that had an effect in this District.

PARTIES

Plaintiff

41. Plaintiff is a current shareholder of Chembio. Plaintiff has continuously held Chembio common stock at all relevant times.

Nominal Defendant Chembio

42. Chembio is a Nevada corporation with its principal executive offices located at 555 Wireless Boulevard, Hauppauge, NY 11788. Chembio's shares trade on the NASDAQ under the ticker symbol "CEMI."

Defendant Eberly

43. Defendant Eberly has served as the Company's President and CEO since March 16, 2020 and as a Company director since May 2, 2020 by appointment of the Board. According to the Amendment No. 2 to the Company's 2019 10-K filed with the SEC on May 6, 2020 (the "May 6 10-K/A"), as of April 29, 2020, Defendant Eberly did not beneficially own any shares of the Company's common stock. However, as of March 16, 2020, the Company entered into an employment agreement with Defendant Eberly dated March 4, 2020 (the "Eberly Employment Agreement"), under the terms of which Defendant Eberly was granted a restricted stock unit award to acquire, without payment of any purchase price, up to 233,589 shares of common stock of the Company which vests in three equal installments as of March 16 of each 2021, 2022, and 2023, subject to Defendant Eberly's continued service with the Company.

44. For the fiscal year ended December 31, 2019, Defendant Eberly was not employed or affiliated with the Company and therefore did not receive compensation. However, according to the terms of the Eberly Employment Agreement, Defendant Eberly will receive at least an annual base salary of $400,000.

45. The Amendment No. 1 to the Company's 2019 10-K filed with the SEC on April 29, 2020 (the "April 29 10-K/A") stated the following about Defendant Eberly:

> Mr. Eberly has served as our Chief Executive Officer and President since March 16, 2020. He was the Managing Director at Solid Rock Principled Capital LLC, a private equity firm focused on biomedical companies, from March 2018 to March 2020. Mr. Eberly served at Meridian Bioscience, Inc. as Executive Vice President

& President, Chief Commercial Officer from July 2016 to February 2018, as President of Meridian Life Science from October 2012 to July 2016, as Chief Commercial Officer from February 2011 to February 2018, as Executive Vice President from 2005 to 2011, as Executive Vice President, General Manager of Meridian Life Science from 2003 to 2005, as Executive Vice President from 2000 to 2003, and as Vice President of Sales and Marketing from 1997 to 2000. Prior to his appointment to Vice President of Sales and Marketing, Mr. Eberly served as the Director of Sales for Meridian. Before joining Meridian, he held sales and marketing positions at Abbott Diagnostics, Division of Abbott Laboratories. Mr. Eberly received a Masters in Business Administration degree from Xavier University and a Bachelor of Science degree in Biochemistry from Juniata College.

Defendant Page

46. Defendant Page served as the Company's interim CEO from January 9, 2020 to March 16, 2020, as Executive Chair of the Board from April 23, 2020 until June 30, 2020, and as a director from 2017 until July 28, 2020.[6] According to the May 6 10-K/A, as of April 29, 2020, Defendant Page beneficially owned 88,815 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on April 29, 2020 was $12.09, Defendant Page owned approximately $1.07 million worth of Chembio stock.

47. For the fiscal year ended December 31, 2019, Defendant Page received $43,500 in in compensation from the Company, which consisted entirely of fees earned or paid in cash.

48. According to the terms of Defendant Page's letter agreement dated January 9, 2020, as amended on June 30, 2020 (the "Page Letter Agreement"), Defendant Page received

[6] Effective January 9, 2020, Defendant Page was appointed as interim Chief Executive Officer, at which time she was no longer considered a non-employee director. Defendant Page served as interim Chief Executive Officer until March 16, 2020 and served as transitional advisor through May 15, 2020. She was appointed to serve as Executive Chair of the Board commencing on April 23, 2020 and served in this capacity until June 30, 2020 pursuant to the terms of an Amendment to Letter Agreement dated June 30, 2020. Under the terms of the Amendment, Defendant Page continued to serve as a Company director until the Annual Meeting of Stockholders of Chembio which was held on July 28, 2020. Also on June 30, 2020, Defendant Page advised the Board of her decision to withdraw as a nominee for election as a director at the Annual Meeting. Subsequently, the Board approved a reduction in the number of directors from five to four effective as of the Annual Meeting.

compensation from the Company, which consisted of a base salary at an annualized rate of $460,000 for serving as the Company's interim CEO, 30,864 shares of common stock,[7] and $76,667 for serving as a temporary consultant on transition matters thereafter.

49. The Company's April 29 10-K/A stated the following about Defendant Page:

> Ms. Page has served as our Executive Chair of the Board since April 23, 2020 and as a Director since 2017. Ms. Page served as our Interim Chief Executive Officer from January 2020 through March 15, 2020 and provided transitional services from March 16, 2020 through April 22, 2020. She has been a Venture Partner at Turret Capital Management, L.P., an international healthcare-focused investment management fund since September 2018. She was the Managing Partner and founder of Vineyard Investment Advisors, LLC, a firm assisting with new product and services development, from 2014 to November 2018. She was the co-founder and director of Consortia Health Holdings LLC, a rehabilitation services provider focused on pelvic disorders, from 2013 to June 2018. Ms. Page previously served as the President, Chief Executive Officer and director of Vermillion, Inc., a developer and manufacturer of novel diagnostic blood tests, from 2006 to 2012. She was the Executive Vice President and Chief Operating Officer of Luminex Corporation, a developer of testing solutions for life science applications, from 2000 to 2003, and Senior Vice President of Roche Biomedical Laboratories, Inc. / Laboratory Corporation of America, a healthcare diagnostic company, from 1988 to 2000. Ms. Page has a Bachelor of Science degree in Medical Technology from the University of Florida, and completed an executive management program at the Kellogg School in Chicago. Ms. Page's experience and relationships in the diagnostic industry, service as our interim Chief Executive Officer, and extensive experience as an executive of other firms in the healthcare industry qualify her to serve as a member of the Board.

Defendant Goldman

50. Defendant Goldman has served as the Company's Executive Vice President and CFO since December 2017. According to the May 6 10-K/A, as of April 29, 2020, Defendant Goldman beneficially owned 129,236 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on April 29, 2020 was $12.09, Defendant Goldman owned approximately $1.56 million worth of Chembio stock.

[7] The Company granted Defendant Page restricted shares under the Company's 2019 Omnibus Incentive Plan. The shares vested upon the appointment of Defendant Eberly as CEO of the Company.

51. For the fiscal year ended December 31, 2019, Defendant Goldman received $347,026 in compensation from the Company. This included $319,039 in salary, a $23,767 bonus, and $4,130 in all other compensation.

52. The Company's April 29 10-K/A stated the following about Defendant Goldman:

> Mr. Goldman has served as our Executive Vice President and Chief Financial Officer since December 2017. He previously served as the Executive Vice President-Corporate Development and Chief Financial Officer at J.S. Held LLC, a construction consulting firm, from May 2015 to May 2017. He was the Global Finance Director for the Delphi Data Connectivity division of Delphi Corp. (now Aptiv plc), an automotive supplier, from October 2014 to April 2015. At Unwired Technology LLC, a tier-1 global automotive electronics manufacturer and distributor, he was the Executive Vice President-Corporate Development and Chief Financial Officer from 2013 to September 2014, the Senior Vice President-Chief Operating and Financial Officer from 2006 to 2013, and Chief Financial Officer from 2005 to 2006. He served as the Chief Financial Officer at EPPCO Enterprises, Inc., a mechanics tools manufacturer, from 2003 to 2005, and as a Senior Manager at Ernst & Young LLP and its successor Cap Gemini Ernst & Young LLC, from 1989 to 2002. Mr. Goldman is a Certified Public Accountant, and received a Bachelor of Science degree in Business-Accountancy from Miami University (Ohio).

Defendant Esfandiari

53. Defendant Esfandiari has served as the Company's Chief Science and Technology Officer since 2004. He previously served as the Director of Research and Development from 2000 to 2004. According to the May 6 10-K/A, as of April 29, 2020, Defendant Esfandiari beneficially owned 128,773 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on April 29, 2020 was $12.09, Defendant Esfandiari owned approximately $1.55 million worth of Chembio stock.

54. For the fiscal year ended December 31, 2019, Defendant Esfandiari received $410,009 in compensation from the Company. This included $373,299 in salary, a $27,983 bonus, and $8,697 in all other compensation.

55. The Company's April 29 10-K/A stated the following about Defendant Esfandiari:

> Mr. Esfandiari has served as our Executive Vice President and Chief Science and Technology Officer since 2004. He was previously our Director of Research and Development from 2000 to 2004. Mr. Esfandiari was Co-founder and Director of Research and Development of Sinovus Biotech AB, a developer of lateral flow technology, from 1997 to 2000. He served as the Director of Research and Development with On-Site Biotech/National Veterinary Institute, a government agency for veterinary medicine, from 1993 to 1997. Mr. Esfandiari received a Master of Science degree in Molecular Biology, and a Bachelor of Science degree in Clinical Chemistry, from Lund University, Sweden.

Defendant Davis

56. Defendant Davis serves as the Company's Chairperson of the Board, and has served as a director since 2007. Previously, she served as the Executive Chairperson of the Board from March 2014 until April 23, 2020. Defendant Davis also serves as the Chair of the Company's Nominating and Corporate Governance Committee, and as a member of the Audit Committee and Compensation Committee. According to the May 6 10-K/A, as of April 29, 2020, Defendant Davis beneficially owned 90,143 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on April 29, 2020 was $12.09, Defendant Davis owned approximately $1.08 million worth of Chembio stock.

57. For the fiscal year ended December 31, 2019, Defendant Davis received $73,500 in compensation from the Company, which consisted entirely of fees earned or paid in cash.

58. The Company's April 29 10-K/A stated the following about Defendant Davis:

> Ms. Davis has served as a Director since 2007 and was Chair of the Board from March 2014 until April 23, 2020. She has been the owner of Davis Design Group LLC, a provider of analytical and visual tools for public policy design, since 2007. She was the Chief Executive Officer of Global Access point, a start-up company with products for data transport, data processing, and data storage network and hub facilities, from 2005 to 2006. She was the Lieutenant Governor of the State of Indiana from 2003 to 2005, and the Controller of the City of Indianapolis from 2000 to 2003. She has been a Financial Advisor to the Mayor of Indianapolis since January 2016. Ms. Davis has a Masters in Business Administration degree from Harvard Business School, and a Bachelor of Science degree in mechanical engineering from the Massachusetts Institute of Technology. Ms. Davis' longstanding quality service as a member of the Board, along with her experience

in business, political and financial industries, qualify her to serve as a member of the board of directors.

Defendant Polan

59. Defendant Polan has served as a Company director since August 2018. She also serves as the Chair of the Company's Compensation Committee and as a member of the Audit Committee and Nominating and Corporate Governance Committee. According to the May 6 10-K/A, as of April 29, 2020, Defendant Polan beneficially owned 26,522 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on April 29, 2020 was $12.09, Defendant Polan owned approximately $320,650 worth of Chembio stock.

60. For the fiscal year ended December 31, 2019, Defendant Polan received $40,500 in compensation from the Company, which consisted entirely of fees earned or paid in cash.

61. The Company's April 29 10-K/A stated the following about Defendant Polan:

> Ms. Polan has served as a Director since August 2018. She has been a Clinical Professor in the Department of Clinical Obstetrics, Gynecology and Reproductive Sciences at Yale University School of Medicine since 2014. She previously was an Adjunct Professor in Obstetrics and Gynecology department at Columbia University School of Medicine from 2007 to 2014, and a Visiting Professor in the same department from 2005 to 2007. Ms. Polan previously served as Chair of Department of Obstetrics and Gynecology at Stanford University School of Medicine from 1990 to 2005. She has been Chair of Scientific Advisory Board in Women's Health for the Procter and Gamble Company since 1997, and Managing Director of Golden Seeds, an angel investing group investing in women-led companies, since 2007. Ms. Polan is the author of more than 130 books, articles and chapters in her areas of research. Ms. Polan has a Master of Public Health (Maternal and Child Health Program) degree from the University of California, Berkeley, a Medical Doctor degree from Yale University School of Medicine, a Doctor of Philosophy degree in Molecular Biophysics and Biochemistry from Yale University School of Medicine and a Bachelor of Arts degree from Connecticut College. Ms. Polan has been a member of the board of directors of Motif Bio plc (AIM/NASDAQ:MTFB), a clinical-stage biopharmaceutical company specializing in developing novel antibiotics, since 2004, and of Quidel Corporation (NASDAQ:QDEL), a developer of point-of-care diagnostic solutions, since 1993. Ms. Polan's extensive medical research experience, knowledge of the diagnostic

> industry, academic credentials, service as a director of other organizations and leadership experience qualify her to serve as a member of the board of directors.

Defendant Potthoff

62. Defendant Potthoff has served as a Company director since May 2018. He also serves as the Chair of the Company's Audit Committee, and as a member of the Compensation Committee and Nominating and Corporate Governance Committee. According to the May 6 10-K/A, as of April 29, 2020, Defendant Potthoff beneficially owned 65,897 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on April 29, 2020 was $12.09, Defendant Potthoff owned approximately $796,694 worth of Chembio stock.

63. For the fiscal year ended December 31, 2019, Defendant Potthoff received $44,500 in compensation from the Company, which consisted entirely of fees earned or paid in cash.

64. The Company's April 29 10-K/A stated the following about Defendant Potthoff:

> Dr. Potthoff has served as a Director since May 2018. He has been the Chief Executive Officer, co-founder and director of Elligo Health Research, a clinical research company, since March 2016. Dr. Potthoff previously served as President and Chief Executive Officer of Theorem Clinical Research Inc., a global contract research organization providing comprehensive clinical services, from 2011 until its acquisition by Chiltern International in September 2015. He was the Chief Operating Officer of INC Research Holdings, Inc. from its acquisition of Tanistry, Inc. in 2001 until its acquisition by private equity investors in 2010. Dr. Potthoff was the Chief Executive Officer and founder of Tanistry, Inc., a contract research organization focused on the central nervous system, from 2000 to 2001. Dr. Potthoff received a Doctor of Philosophy degree in Psychology from the University of Texas-Austin, a Master of Arts degree in Psychology from the University of Texas-Austin, and a Bachelor of Arts degree in Psychology from the University of Texas-Austin. Mr. Potthoff's extensive experience, knowledge and relationships in clinical research and other aspects of the diagnostics and pharmaceutical industries, as well as his experience as a chief executive officer, qualify him to serve as a member of the board of directors.

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

65. By reason of their positions as officers and/or directors of Chembio, and because of their ability to control the business and corporate affairs of Chembio, the Individual Defendants owed Chembio and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Chembio in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Chembio and its shareholders so as to benefit all shareholders equally.

66. Each director and officer of the Company owes to Chembio and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligations of fair dealing.

67. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Chembio, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein.

68. To discharge their duties, the officers and directors of Chembio were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

69. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Chembio, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the

Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

70. As senior executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, including the dissemination of false information regarding the Company's business, prospects, and operations, and had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful and accurate information.

71. To discharge their duties, the officers and directors of Chembio were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Chembio were required to, among other things:

(a) ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of New York and the United States, and pursuant to Chembio's Code of Business Conduct and Ethics (the "Code of Ethics");

(b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) remain informed as to how Chembio conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

(d) establish and maintain systematic and accurate records and reports of the business and internal affairs of Chembio and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

(e) maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Chembio's operations would comply with all applicable laws and Chembio's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;

(f) exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;

(g) refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(h) examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

72. Each of the Individual Defendants further owed to Chembio and the shareholders the duty of loyalty requiring that each favor Chembio's interest and that of its shareholders over

their own while conducting the affairs of the Company and refrain from using their position, influence or knowledge of the affairs of the Company to gain personal advantage.

73. At all times relevant hereto, the Individual Defendants were the agents of each other and of Chembio and were at all times acting within the course and scope of such agency.

74. Because of their advisory, executive, managerial, and directorial positions with Chembio, each of the Individual Defendants had access to adverse, non-public information about the Company.

75. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Chembio.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

76. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The Individual Defendants caused the Company to conceal the true facts as alleged herein. The Individual Defendants further aided and abetted and assisted each other in breaching their respective duties.

77. The purpose and effect of the conspiracy, common enterprise, and common course of conduct was, among other things, to: (i) facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, and violations of the Exchange Act; (ii) conceal adverse information concerning the Company's operations, financial condition, legal compliance, future business prospects and internal controls; and (iii) artificially inflate the Company's stock price.

78. The Individual Defendants accomplished their conspiracy, common enterprise, and common course of conduct by causing the Company purposefully or recklessly to conceal material

facts, fail to correct such misrepresentations, and violate applicable laws. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants who is a director of Chembio was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and common course of conduct complained of herein.

79. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each of the Individual Defendants acted with actual or constructive knowledge of the primary wrongdoing, either took direct part in, or substantially assisted in the accomplishment of that wrongdoing, and was or should have been aware of his or her overall contribution to and furtherance of the wrongdoing.

80. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants, and of Chembio, and was at all times acting within the course and scope of such agency.

CHEMBIO'S CODE OF ETHICS

81. The Company's Schedule 14A filed with the SEC on June 16, 2020 (the "2020 Proxy Statement") states, in relevant part:

> **Code of Business Conduct and Ethics**
>
> We have a Code of Business Conduct and Ethics, or the Conduct Code, **applicable to all directors, officers and employees of Chembio and its subsidiaries**. We have posted the Conduct Code on our website at *www.chembiodiagnosticsinc.gcs-web.com/static-files/bca4f259-b35e-4280-a17f-2509fb6ff007*. We will post any amendments to the Conduct Code on our website. In accordance with the requirements of the SEC and Nasdaq, we will also post waivers applicable to any of our officers or directors from provisions of the Conduct Code on our website. We have not granted any such waivers to date.

> We have implemented whistleblower procedures, which establish format protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures are to be communicated to the audit committee or our Chief Executive Officer and President.
>
> (Emphasis added, except heading.)

82. The Company's Code of Ethics states that "[t]he standards set forth in this Code are linked closely to our corporate vision, strategies and value" and that "[a]ll of our employees must conduct themselves accordingly and seek to avoid even the appearance of improper behavior." The Code of Ethics also states it is "intended to provide guidance to persons functioning in managerial or administrative capacities, as well as to all employees."

83. The Code of Ethics further provides that:

> The integrity, reputation, and profitability of the Company ultimately depend upon the individual actions of our employees, representatives, officers, directors, agents, and consultants. It is the policy of the Company to comply with all applicable laws and to adhere to ethical standards in the conduct of our business. Each employee is expected to read and understand this Code, uphold these standards in daily activities and take personal responsibility for compliance with all applicable policies and procedures.

84. In a section titled, "Record-Keeping," the Code of Ethics states the following:

> The Company requires honest and accurate recording and reporting of information in order to make responsible business decisions. Certain employees may use business expense accounts, which must be documented and recorded accurately. If you are not sure whether a certain expense is legitimate, ask your supervisor.
>
> All of the Company's books, records, accounts, and financial statements must be maintained in reasonable detail, must appropriately reflect the Company's transactions, and must conform both to applicable legal requirements and to the Company's system of internal controls. Unrecorded or "off the books" funds or assets should not be maintained unless permitted by applicable law or regulation.
>
> Business records and communications often become public, and we should avoid exaggeration, derogatory remarks, guesswork, or inappropriate characterizations of people and companies that can be misunderstood. This applies equally to e-mail, internal memos, and formal reports. Records should always be retained or destroyed according to the Company's record retention policies. In accordance with those

> policies, in the event of litigation or governmental investigation please consult the Company's Chief Executive Officer or Chief Financial Officer.

85. In a section titled, "Compliance with Laws, Rules and Regulations," the Code of Ethics states the following, in relevant part:

> Obeying the law, both in letter and in spirit, is the foundation on which this Company's ethical standards are built. All employees must respect and obey the laws of the cities, states and countries in which we operate. Although not all employees are expected to know the details of these laws, it is important to know enough to determine when to seek advice from supervisors, managers or other appropriate personnel. Because individual violations may also subject the Company to civil or criminal liability or the loss of business, the Company takes legal compliance measures seriously and works diligently to enforce them.

86. The 2020 Proxy Statement states, in relevant part:

> **Board Oversight of Risk**
>
> The board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable the board to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.
>
> The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes the Chief Financial Officer reporting directly to the audit committee at least quarterly to provide an update on management's efforts to manage risk.
>
> Matters of significant strategic risk, including cybersecurity risks, are considered by the board as a whole.

87. In violation of the Code of Ethics, the Individual Defendants conducted little, if any, oversight of the Company's engagement in the Individual Defendants' scheme to issue materially false and misleading statements to the public and to facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, and

violations of the Exchange Act. Also in violation of the Code of Ethics, the Individual Defendants failed to maintain the accuracy of Company records and reports, comply with laws and regulations, conduct business in an honest and ethical manner, and properly report violations of the Code of Ethics.

THE INDIVIDUAL DEFENDANTS' MISCONDUCT

Background

88. Incorporated in Nevada and headquartered in Hauppauge, New York, Chembio is a point-of-care diagnostics company that develops and commercializes patented technology platforms, including DPP, aimed at, among other things, detecting and diagnosing infectious diseases.

89. Chembio was originally founded in 1985 as a private company and became a publicly traded company in 2004.

90. According to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2018 (the "2018 10-K"), historically, Chembio's primary business was the design and sale of rapid diagnostic tests for, among other infectious diseases, HIV, HIV-Syphilis, Syphilis, Zika, Leishmaniasis, Chagas, and Ebola to customers such as hospitals, governmental and public health entities, non-governmental organizations, medical professionals, and retail establishments primarily located in the United States, Brazil, Europe, Malaysia and Mexico. However, according to the 2018 10-K and 2019 10-K, Chembio incurred an operating loss each year from 2014 through 2019.

91. In late 2019, the novel coronavirus, COVID-19, began spreading through Wuhan, China. COVID-19's rampant spread quickly turned into a worldwide pandemic that, to date, has resulted in millions of infections, hundreds of thousands of deaths, and untold devastation to the global economy and many national healthcare systems.

92. Accurate and reliable methods for mass testing for COVID-19 have become critically important tools for containing the outbreak of the virus, as they provide much-needed data to public officials to help determine what public policy measures should be implemented.

93. Given that fast, dependable and precise testing is in extraordinary demand, Chembio was in the fortuitous position to utilize its proprietary technology, intellectual property, and extensive experience in the diagnostic testing space to take advantage of this global public health crisis and financially benefit from the outbreak of the virus.

94. In January 2020, Chembio refocused its business strategy on the development and commercialization of its proprietary DPP technology for a rapid antibody test for COVID-19. Accordingly, Chembio was among the first companies to begin developing a rapid antibody COVID-19 test.

95. On March 12, 2020, Chembio published the March 12 Press Release 1, announcing that the Company had entered into a strategic partnership with LumiraDx, with the goal of developing a diagnostic test for the detection of the COVID-19 virus and IgM and IgG antibodies using its DPP. On this news, Chembio's shares increased during after-hours trading from $3.10 per share at close on March 11, 2020, to an opening share price of $4.19 on March 12, 2020.

96. According to a press release circulated by Chembio on March 20, 2020, titled "Chembio Diagnostics Receives $4 Million Purchase Order from Bio-Manguinhos for Production of DPP COVID-19 IgM/IgG System in Brazil" the Company received an order from Bio-Manguinhos, a subsidiary of a company that is largely responsible for meeting the demands of Brazil's national public health system, to purchase approximately $4 million dollars' worth of the Company's rapid COVID-19 antibody test.

97. On this news, the Company's stock began to surge in value. In the days leading up to the Company's March 20, 2020 announcement, the Company's stock traded between $2.00 and $3.00 per share. By March 23, 2020, the Company's stock closed at $4.00 per share and then climbed to $5.60 per share by March 27, 2020.

98. On March 31, 2020, through a press release titled "Chembio Announces Launch of DPP COVID-19 Serological Point-of-Care Test" (the "March 31 Press Release"), Chembio announced the U.S. launch of the rapid DPP COVID-19 serological point-of-care test for the detection of IgM and IgG antibodies.

99. On April 8, 2020, the World Health Organization published a scientific brief titled "Advice on the use of point-of-care immunodiagnostic tests for COVID-19"[8] which indicated, among other things, that "WHO does not recommend the use of antibody-detecting rapid diagnostic tests for patient care." The brief stated the following:

> In response to the growing COVID-19 pandemic and shortages of laboratory-based molecular testing capacity and reagents, multiple diagnostic test manufacturers have developed and begun selling rapid and easy-to-use devices to facilitate testing outside of laboratory settings. These simple test kits are based either on detection of proteins from the COVID-19 virus in respiratory samples (e.g. sputum, throat swab) or detection, in blood or serum, of human antibodies generated in response to infection.
>
> WHO applauds the efforts of test developers to innovate and respond to the needs of the population.
>
> However, before these tests can be recommended, they must be validated in the appropriate populations and settings. Inadequate tests may miss patients with active infection or falsely categorize patients as having the disease when they do not, further hampering disease control efforts. **At present, based on current evidence, WHO recommends the use of these new point-of-care immunodiagnostic tests only in research settings. They should not be used in any other setting, including for clinical decision-making, until evidence supporting use for specific indications is available.**

[8] https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19 (last visited September 10, 2020).

WHO continues to evaluate available immunodiagnostics tests for COVID-19 and will update this scientific brief when necessary.

Rapid diagnostic tests based on antigen detection

One type of rapid diagnostic test (RDT) detects the presence of viral proteins (antigens) expressed by the COVID-19 virus in a sample from the respiratory tract of a person. If the target antigen is present in sufficient concentrations in the sample, it will bind to specific antibodies fixed to a paper strip enclosed in a plastic casing and generate a visually detectable signal, typically within 30 minutes. The antigen(s) detected are expressed only when the virus is actively replicating; therefore, such tests are best used to identify acute or early infection.

How well the tests work depends on several factors, including the time from onset of illness, the concentration of virus in the specimen, the quality of the specimen collected from a person and how it is processed, and the precise formulation of the reagents in the test kits. Based on experience with antigen-based RDTs for other respiratory diseases such as influenza, in which affected patients have comparable concentrations of influenza virus in respiratory samples as seen in COVID-19, the sensitivity of these tests might be expected to vary from 34% to 80%.

Based on this information, half or more of COVID-19 infected patients might be missed by such tests, depending on the group of patients tested. These assumptions urgently require further study to understand whether they are accurate. Additionally, false-positive results – that is, a test showing that a person is infected when they are not – could occur if the antibodies on the test strip also recognize antigens of viruses other than COVID-19, such as from human coronaviruses that cause the common cold. If any of the antigen detection tests that are under development or commercialized demonstrate adequate performance, they could potentially be used as triage tests to rapidly identify patients who are very likely to have COVID-19, reducing or eliminating the need for expensive molecular confirmatory testing.

With the limited data now available, **WHO does not currently recommend the use of antigen-detecting rapid diagnostic tests for patient care, although research into their performance and potential diagnostic utility is highly encouraged**.

Rapid diagnostic tests based on host antibody detection

There is another, more common type of rapid diagnostic test marketed for COVID-19; a test that detects the presence of antibodies in the blood of people believed to have been infected with COVID-19. Antibodies are produced over days to weeks after infection with the virus. The strength of antibody response depends on several factors, including age, nutritional status, severity of disease, and certain

medications or infections like HIV that suppress the immune system. In some people with COVID-19, disease confirmed by molecular testing (e.g. reverse transcription polymerase chain reaction: RT-PCR), weak, late or absent antibody responses have been reported. Studies suggest that the majority of patients develop antibody response only in the second week after onset of symptoms. This means that a diagnosis of COVID-19 infection based on antibody response will often only be possible in the recovery phase, when many of the opportunities for clinical intervention or interruption of disease transmission have already passed. Antibody detection tests targeting COVID-19 may also cross-react with other pathogens, including other human coronaviruses [sic] and give false-positive results. Lastly, there has been discussion about whether RDTs detecting antibodies could predict whether an individual was immune to reinfection with the COVID-19 virus. There is no evidence to date to support this.

Tests to detect antibody responses to COVID-19 in the population will be critical to support the development of vaccines, and to add to our understanding of the extent of infection among people who are not identified through active case finding and surveillance efforts, the attack rate in the population, and the infection fatality rate. For clinical diagnosis, however, such tests have limited utility because they cannot quickly diagnose acute infection to inform actions needed to determine the course of treatment. Some clinicians have used these tests for antibody responses to make a presumptive diagnosis of recent COVID-19 disease in cases where molecular testing was negative but where there was a strong epidemiological link to COVID-19 infection and paired blood samples (acute and convalescent) showing rising antibody levels.

Based on current data, **WHO does not recommend the use of antibody-detecting rapid diagnostic tests for patient care but encourages the continuation of work to establish their usefulness in disease surveillance and epidemiologic research**.

Next steps

- Molecular (e.g. PCR) testing of respiratory tract samples is the recommended method for the identification and laboratory confirmation of COVID-19 cases. COVID-19 molecular diagnostic products are being evaluated for quality and safety through the WHO Prequalification Emergency Use Listing Procedures and through a collaboration with the Foundation for Innovative New Diagnostics (FIND). WHO guidance documents for detection of COVID-19 have been published: WHO Guidance on Laboratory testing for COVID-19 in suspected human cases. In addition, guidance on how testing might be rationalized when lack of reagents or testing capacity necessitates prioritization of certain populations or individuals for testing is also available.
- To inform WHO policy on the use of immunodiagnostic rapid tests for COVID-19, WHO is working with our global laboratory expert network, and closely reviewing

the results of laboratory and clinical studies planned and implemented by reference laboratories, academic groups and non-governmental organizations.

- Target product profiles for desired COVID-19 diagnostics to inform research and development efforts are in development.
- WHO will continue to work with research groups, other agencies, and Member States to develop and interpret data that might indicate specific areas where such tests can be useful for clinical management of cases, epidemiologic understanding, and/or infection control.

(Internal citations omitted.)

100. By way of press release dated April 9, 2020 titled "Chembio Diagnostics and Stony Brook Medicine Collaborate to Identify Coronavirus Survivors" (the "April 9 Press Release") the Company announced that Stony Brook Medicine had selected Chembio's rapid antibody test to help identify persons who have recovered from COVID-19 for use in its FDA-approved investigation to determine whether those persons' antibodies can help treat patients with an active COVID-19 infection. Also in April 2020, Chembio's rapid COVID-19 antibody test was approved for manufacture and sale in Brazil.

101. By letter dated April 14, 2020, the FDA authorized the issuance of an EUA to Chembio to utilize and distribute its rapid COVID-19 antibody tests. The Company issued the April 15 Press Release one day later announcing it had received regulatory approval from the FDA.

102. On this news, the Company's stock price again began to swell from a closing price of $9.42 per share on April 14, 2020 to a high of $15.54 just ten days later, on April 24, 2020.

103. On April 19, 2020, the New York Times published an article titled "Antibody Test, Seen as Key to Reopening Country, Does Not Yet Deliver" (the "NYT Article")[9] casting doubt on the efficacy of all COVID-19 antibody tests that were available to the public at the time. The NYT Article stated, in pertinent part:

[9] https://www.nytimes.com/2020/04/19/us/coronavirus-antibody-tests.html (last visited September 10, 2020).

"People don't understand how dangerous this test is," said Michael T. Osterholm, an infectious disease expert at the University of Minnesota. **"We sacrificed quality for speed, and in the end, when it's people's lives that are hanging in the balance, safety has to take precedence over speed."**

Even as government agencies, companies and academic researchers scramble to validate existing tests and create better ones, there are doubts they can deliver as promised. **Most tests now available mistakenly flag at least some people as having antibodies when they do not, which could foster a dangerously false belief that those people have immunity.**

…

Recent testing around the country demonstrates the challenges of using the new products. At the Chicago hospital, for example, the city's Public Health Department intervened, warning that it should not use antibody tests to determine whether emergency workers were actively infected.

Soon after it helped screen the Rose Law Group, the firm in Arizona, a lab stopped providing rapid tests to other clients, fearing they might not comply with federal guidelines, and switched to more sophisticated lab-based tests.

In Laredo, officials discovered the tests they received were woefully inadequate. The local health department found them to have a reliability of about 20 percent, far from the 93 to 97 percent the company had claimed. A police investigation led to a federal seizure of the tests.

"The city was disappointed, but during a time of crisis, we are doing everything possible to scour the earth to have tests available for the public," said Rafael Benavides, the city's public information officer.

"It's a real mess," Dr. Osterholm said. "This is the wild, wild West in terms of testing, and at a time when we need real definition of what these tests mean."

…

Rapid tests are by far the easiest to administer. But they are also the most unreliable — so much so that the World Health Organization recommends against their use.

Most are manufactured in China. Reports of countries that quickly bought millions have just as swiftly been followed by accounts of poor performance.

For example, Britain recently said the millions of rapid tests it had ordered from China were not sensitive enough to detect antibodies except in people who were severely ill. In Spain, the testing push turned into a fiasco last month after the initial

batch of kits it received had an accuracy of 30 percent, rather than the advertised 80 percent. In Italy, local officials have begun testing even before national authorities have validated the tests.

"The problems mainly happen with rapid tests," said Dr. Giorgio Palù, an Italian microbiologist and former president of the European Society for Virology. "They will never be able to tell the spread of the virus because they do not have the required sensitivity and specificity."

Germany, which has emerged as a model among Western democracies in its efforts to curb the spread of the virus, is pursuing one of the most ambitious antibody studies, striving to test its entire population. It is a leader in the technology, has made its own antibody tests and conducted extensive diagnostic screening from the beginning.

This month, the F.D.A. warned that some firms marketing their antibody tests in the United States were falsely claiming that they had formal federal approval, or that they could diagnose Covid-19.

In an effort to speed up access, the F.D.A. apparently did not fully consider how these tests would be administered. The agency released a guidance document saying that antibody tests could be performed at "point-of-care" settings, indicating that doctors, nurses and others could give them to patients in their offices. But agency officials also acknowledged that under federal law, if a test has not been authorized by the agency, it must be conducted in so-called high-complexity laboratories, like some large commercial facilities or public health labs. The officials decline to provide additional clarification.

"If you are getting an antibody test and it's being conducted in your physician's office, it's a red flag," said Kelly Wroblewski, director of the infectious disease programs for the Association of Public Health Laboratories.

No action has been taken against doctors, but as companies realized the ambiguity of the federal guidelines, some changed course, shifting to lab-based tests or pursuing formal federal approval, which would allow their products to be used at doctors' offices and even at home.

The F.D.A. has received requests for emergency-use authorization from 120 antibody-testing developers. So far it has granted formal approval to just four: Cellex, Ortho Clinical Diagnostics, Chembio Diagnostic Systems and the Mount Sinai Laboratory.

…

In Search of a Test That Works

> While political leaders and some health officials say that antibody testing will be essential to reopening the country, it is unlikely to meet expectations anytime soon.
>
> Less than 5 percent of the U.S. population may be infected, and even in hot zones like New York or New Orleans, the prevalence may not be higher than 10 to 15 percent, according to Dr. Osterholm. In China, early screening in hard-hit Wuhan indicates that only about 3 percent of the population has antibodies against the new coronavirus.
>
> When the proportion of people exposed is that low, the tests' false positive rate — signaling antibodies where there are none — can limit the tests' utility.
>
> **Even Cellex's F.D.A.-authorized test has a false positive rate of about 5 percent. That is still a significant margin of error: In a community where 5 percent of people have had the virus, Dr. Osterholm said, there would be as many false positives as true ones.**
>
> **"What are you going to do with that? Are you going to say you're not going to distance?" he said. "I don't think that would give me peace of mind at all."** Some tests on the market without federal approval are likely to have even higher false positive rates. It is unclear how these companies have validated their tests or how they stack up against one another.
>
> Researchers at the National Institutes of Health are validating some of the tests in cooperation with the F.D.A. A Danish group published a small analysis of nine tests and found, as might be expected, that some performed better than others. A research group backed by the Chan Zuckerberg Initiative is working to assess all available tests using the same set of samples for each, with early results expected next week.
>
> **"There's an urgent need to know which of these tests we can rely on — I think the only way we can know is head-to-head testing," said Dr. Alexander Marson, one of the leaders of the project and a microbiologist at the University of California, San Francisco.**

(Emphasis added.)

104. According to the FDA's June 16 Letter, the FDA expressed concerns to the Company as early as April 29, 2020 regarding the accuracy of Chembio's rapid COVID-19 antibody tests as a result of data submitted by the Company itself as well as poor performance observed in clinical trials performed by the Independent Evaluators. Specifically, the Independent Evaluators observed a positive percent agreement or sensitivity rate of 57.1% for IgM, 78.6% for

IgG, and 82.1% for combined IgM/IgG. The overall negative percent agreement or specificity was 81.2%.

105. On or about April 29, 2020, Chembio submitted additional data to the FDA in response to the FDA's concerns over the accuracy of Chembio's rapid COVID-19 antibody test.

106. On May 4, 2020, Chembio issued a press release titled "Chembio Diagnostic Attains CE Marking for DPP COVID-19 System for IgG and IgM Antibodies" (the "May 4 Press Release 1") announcing that its COVID-19 antibody test attained the CE Marking, enabling its sale in the European Union and the Caribbean region.[10]

107. On May 4, 2020, the Company filed its quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2020 with the SEC (the "1Q20 10-Q"), which, among other things, set forth the Company's financial woes for the fiscal quarter ended March 31, 2020, stating the following:

> The global COVID-19 pandemic significantly affected our operating results for the three months ended March 31, 2020. We anticipated that, in addition to the business disruption and general economic effects caused by the pandemic, a substantial portion of the funding that would otherwise have been available for testing for infectious diseases addressed by our diagnostic tests, such as the human immunodeficiency virus or HIV, would be redirected to testing for the novel coronavirus that causes COVID-19. In February 2020 we began the process of shifting substantially all of our resources to leverage our DPP lateral flow technology to address the acute and escalating need for an accurate diagnostic test for COVID-19. The diminished focus on our existing product portfolio, as well as the extensive economic disruption caused by the COVID-19 pandemic, was reflected in our first quarter results as compared to the prior year period, as total revenue decreased 19.7% to $6.9 million and product sales decreased 13.7% to $5.7 million.

108. Also on May 4, 2020, the Company put out another press release titled "Chembio Diagnostics Reports First Quarter 2020 Financial Results" (the "May 4 Press Release 2") in which

[10] Excluding Puerto Rico.

it announced its first quarter 2020 financial results disclosing that total revenue for the quarter decreased by 20% compared to the prior year period, net product sales for the quarter decreased 14% comparted to the prior year period, and license and royalty revenue together with R&D and grant revenue for the quarter decreased 40% compared to the prior year period. Moreover, the Company divulged that net loss for the quarter was a staggering 78% more than it had been for the prior year period.

109. Only one week after the FDA shared its concerns related to the test's accuracy with the Company and about two days after disclosing abysmal financial results, the Company filed a preliminary prospectus supplement on Form 424B5 with the SEC dated May 6, 2020 (the "May 6 Form 424B5") in connection with the Company's proposed secondary public offering of an undetermined number of shares of its common stock. Two days later, on May 8, 2020, the Company filed a prospectus supplement on Form 424B5 with the SEC dated May 7, 2020 (the "May 8 Form 424B5," and together with the May 6 Form 424B5, the "May 2020 Offering Documents").

110. The Company also circulated a press release on May 6, 2020 titled "Chembio Diagnostics Announces Proposed Public Offering of Common Stock" announcing a proposed secondary public offering of an undetermined number of shares of its common stock. The Company disclosed, in relevant part, that it intended to use the net proceeds to "expand its sales force to support growth, to increase its manufacturing capacity and for other general corporate purposes."

111. The Company filed a Form 8-K/A with the SEC on May 11, 2020 in connection with the sale and issuance of up to 2,619,593 shares of the Company's common stock.

112. The Company also issued a press release on May 11, 2020, titled "Chembio Diagnostics Announces Closing of Public Offering of Common Stock" announcing the closing of its previously announced registered direct offering of its common stock. According to the press release, the Company offered 2,619,593 shares of common stock.[11] The Company's shares of common stock had been priced at $11.75 per share, and total gross proceeds from the offering equaled approximately $30.8 million.

113. According to the FDA's June 16 Letter, the Company submitted additional data to the FDA on May 15, 2020 in further response to the FDA's above-referenced concerns regarding the accuracy of Chembio's rapid COVID-19 antibody tests.

114. On May 18, 2020, the Company disseminated a press release titled "Chembio Diagnostics Announces US Distribution Agreement to Expend Reach of DPP COVID-19 Serological Test with Thermo Fisher Scientific's Healthcare Channel" (the "May 18 Press Release") announcing it had partnered with Thermo Fisher Scientific's healthcare channel to distribute Chembio's rapid COVID-19 antibody test.

115. According to the FDA's June 16 Letter, the FDA contacted Chembio on May 22, 2020 explaining its concern that the data submitted by the Company itself as well as observed by the Independent Evaluators "suggest significant performance concerns" with the Company's rapid COVID-19 antibody testing device, "which may put patients at unreasonable risk of harm due to inaccurate results."

[11] Includes 281,125 shares issued pursuant to the partial exercise by the underwrites of their option to purchase additional shares of common stock from Chembio. The Company granted the underwriters a 30-day option to purchases up to an additional 350,770 shares of common stock at the public offering price less the underwriting discounts and commissions.

116. According to the FDA's June 16 Letter, Chembio responded to the FDA on May 24, 2020 stating that an investigation had been performed to better understand and confirm the findings of the clinical trials performed by the Independent Evaluators. Based on the results of the Company's investigation, Chembio changed the apparent diffusion coefficient ("ADC")[12] cut-off for the magnetic resonance imaging ("MRI") (which was used in the NCI evaluation) from 25 to 35. Further, the Company explained that its re-analysis of the data from the clinical trials performed by the Independent Evaluators using the new ADC cut-off suggested that the specificity of the Company's rapid COVID-19 antibody testing device could be improved from 81.2% to 93.5% and that the performance of the device with the MRI with the revised ADC cut-off produces results equivalent to those of the MRI using the original ADC cut-off that the FDA authorized on April 14, 2020.

117. In mid-June 2020, The New Yorker published an article entitled "How Utah's Tech Industry Tried to Disrupt Coronavirus Testing" in which it explained that "sensitivity," "specificity," and the "limit of detection" are all analytic measures of a test's performance.

118. According to the article, sensitivity "measures how well a test picks up true positives" and specificity "measures how well a test identifies true negatives."

119. Regarding the limit of detection, the New Yorker article explained, in relevant part, that:

> The limit of detection, or L.O.D., describes the concentration of a target pathogen that must be present for a test to consistently return a positive result. A test with a high L.O.D. may detect people who are acutely ill, when they are carrying a high viral load, but struggle to identify patients who are at the beginning or end of their

[12] ADC is a measure of the magnitude of diffusion (of water molecules) within tissue, and is commonly clinically calculated using MRI with diffusion-weighted imaging ("DWI"). DWI is a form of MRI based upon measuring the random Brownian motion of water molecules within a voxel of tissue. In general simplified terms, highly cellular tissues or those with cellular swelling exhibit lower diffusion coefficients.

> illness, when the viral load is lower. Steven Hinrichs, the former director of the Nebraska Public Health Laboratory [stated] that, for a disease like COVID-19, which appears to do much of its spreading while people are presymptomatic, it is important to have tests that can identify people in the early stages of infection, so that people can be isolated and their contracts traced.

120. In light of, among other things, the pressure to sustain the Company's operations and its competitive advantage over sophisticated competitors, the Individual Defendants rushed the Company's rapid COVID-19 antibody tests to market without first competently verifying the accuracy of the tests.

121. The Individual Defendants knew Chembio's rapid COVID-19 antibody tests were less than 100% accurate after 11 days post the onset of symptoms and knew that the accuracy of the tests had not yet been substantiated at the time the Individual Defendants issued their false claims, including the claim that the Company's tests were high quality and 100% accurate after 11 days post the onset of symptoms. Additionally, the Individual Defendants knew that a test generating accuracy rates even between 95% and 99%, for example, would offer significantly less value to public officials working to quickly contain the virus and its devastating effects, as opposed to a test with flawless precision—as explained herein.

122. Yet, as described herein, and as the Individual Defendants were aware, the FDA considered the data submitted by the Company itself as well as generated from the clinical trials performed by the Independent Evaluators in April and May 2020 problematic and likely inadequate to support and maintain its approval of the Company's rapid COVID-19 antibody test without taking necessary steps, like revocation, to protect the public's health. The Individual Defendants knowingly circulated false statements and omissions of material fact regarding the accuracy of the Company's rapid COVID-19 antibody test to the public in order to gain a

competitive advantage over other formidable biotechnology companies and to capitalize on the inimitable financial opportunity presented by the pandemic.

False and Misleading Statements

March 12, 2020 Press Releases & Conference Call

March 12, 2020 Press Release #1

123. On March 12, 2020, Chembio issued the March 12 Press Release 1, announcing that the Company had entered into a strategic partnership with LumiraDx, a company, according to its website, that is focused on "developing, manufacturing, and commercializing industry leading point-of-care diagnostic platforms," with the goal of developing a diagnostic test for the detection of the COVID-19 virus and IgM and IgG antibodies using its DPP. Defendant Page commented, in relevant part:

> "We are very excited to join with LumiraDx in this strategic partnership, which **demonstrates our scientific expertise and the versatility of our DPP platform**," stated Gail Page, Chembio's Interim Chief Executive Officer. "Through our joint efforts, **we expect the new products to provide comprehensive solutions to the new demands surrounding the worldwide testing needs for COVID-19.**"

(Emphasis added.)

March 12, 2020 Press Release #2

124. That same day, the Company published a second press release (the "March 12 Press Release 2") related to its 2019 fourth quarter financial results, indicating that the Company suffered a decrease in total full year 2019 revenue of 0.3% and a decrease of both product and total revenue for the fourth quarter 2019. Defendant Page commented, in relevant part:

> "**As we look to 2020, we are very excited to partner up with LumiraDx and combine our collective scientific expertise to develop point-of-care tests for COVID-19. We are confident our combined solutions will be the preferred approach for healthcare providers to detect and monitor this pandemic.** In addition, we are pleased to have appointed Richard Eberly as CEO to lead the next phase of Chembio's growth. He is a diagnostics industry veteran who brings to the

> company years of experience commercializing and growing many product platforms. We are confident we have the right team and technology to extend our leadership in point-of-care diagnostics, grow revenues, and create long-term shareholder value."

(Emphasis added.)

March 12, 2020 Investor Conference Call

125. Chembio held an investor conference call on March 12, 2020 (the "March 12 Conference Call") to discuss its above-referenced partnership with LumiraDx and the Company's fourth quarter and 2019 financial results. At the beginning of the call, Defendant Page reiterated statements made in the March 12 Press Release 1 related to the expansion of the Company's COVID-19 antibody testing, stating, in relevant part:

> We entered into a worldwide strategic partnership with LumiraDX Limited to develop point-of-care diagnostic tests for the detection of the COVID-19 virus as well as IgM and IgG antibodies on both the LumiraDX and Chembio DPP platforms. This expands and strengthens our existing relationship with LumiraDX and further **demonstrates our scientific expertise and the versatility of our DPP platform**. **Through our joint efforts, we expect the new product to provide comprehensive solutions to the new demand surrounding the worldwide testing needs for COVID-19**.

(Emphasis added.)

126. On the conference call, Defendant Page responded to a question posed by an analyst from Craig-Hallum Capital Group LLC regarding the structure of the partnership with LumiraDx, stating, in relevant part:

> That's the largest question. I need to be careful here because how we interact, what we do with Lumira, we want to respect their confidentiality, if you will. What I can say is that, if you'll notice that this is an entirely new agreement. This is a strategic partnership. This is one where both boxes will have the test, but Lumira will be selling the DPP as well as their own box. There's a lot more in this agreement that, again, properly incentivizes and rewards both of us for getting the test to the market in a very expeditious manner. **But also, again, to point out that we're all very focused taking all the intelligence of LumiraDX and all the intelligence here to make sure we have something that's commercially viable. It's just like years ago, we had to get a test for the flu, right?** So sometimes you go to doctor, you

> need to know, do I have the flu or don't I, right? There's all kinds of new viruses. And that goes back to, well, why do you need to know, what you need to know where they say stay home and you don't get on the plane, if you got the flu or you don't, whatever. **So I think that we have a lot of expertise in bringing these types of things to the market. We have the platform,** they have the collective intelligence. So I think it's -- we're very optimistic, and we're sorting out all the details.

(Emphasis added.)

March 13, 2020 Form 10-K

127. On March 13, 2020, the Company filed the 2019 10-K. The 2019 10-K was signed by Defendants Page, Goldman, Davis, Polan, and Potthoff, and contained certifications pursuant to Rule 13a-14(a) and 15d-14(a) under the Exchange Act and the Sarbanes-Oxley Act of 2002 ("SOX") signed by Defendants Page and Goldman attesting to the accuracy of the financial statements contained therein, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

128. The 2019 10-K stated the following regarding the Company's internal controls:

Management's Report on Internal Control Over Financial Reporting

> Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and effected by the board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:
>
> - pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
> - provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made in accordance with authorizations of management and directors of the company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. As a result, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our Interim Chief Executive Officer and Chief Financial Officer, our management evaluated the effectiveness of our internal control over financial reporting as of December 31, 2019. In making their assessment of internal control over financial reporting, our management used the criteria described in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our evaluation included documenting, evaluating and testing of the design and operating effectiveness of our internal control over financial reporting. **Based on this evaluation, we concluded that our controls over financial reporting were effective as of December 31, 2019**.

Previously Identified Material Weaknesses in Internal Control Over Financial Reporting

None.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Securities Exchange Act of 1934 during the period covered by this Annual Report on Form 10-K that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(Emphasis added in bold, not italics.)

March 31, 2020 Press Release

129. On March 31, 2020, the Company issued the March 31 Press Release, which announced the U.S. launch of the rapid DPP COVID-19 serological point-of-care test for the detection of IgM and IgG antibodies, stating, in pertinent part:

> **The ability of the DPP platform to provide numerical results can aid clinicians in determining current or past exposure to the COVID-19 virus and monitoring infection progression, while avoiding the human interpretation errors associated with visual readings.**
>
> …
>
> **"The results and data from our DPP COVID-19 test can help improve clinical outcomes through the management of individual patients by enabling clinicians to understand the likelihood of past and present infection and to manage populations as a whole as a surveillance test," stated Richard Eberly, Chief Executive Officer of Chembio. "Our measured approach has positioned us to offer a viable and sustainable long-term solution for clinicians.** We expect to begin shipping product in April 2020, and we will continue to work with our partner LumiraDx to provide DPP COVID-19 tests with the ability to scale based upon market demand."
>
> "We are excited that, through diligent collaboration with the FDA, our test will be distributed as authorized by the FDA Notification process under the public health emergency guidance issued on March 16, 2020," stated Gail S. Page, Chembio director. "This is another example of Chembio's ability to respond in an expeditious manner to global pandemics with differentiated solutions, as demonstrated previously with Zika and Ebola."
>
> …
>
> Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases. **The company's patented DPP technology platform, which uses a small drop of blood from the fingertip, provides high-quality, cost-effective results in approximately 15 minutes**.

(Emphasis added.)

April 9 Press Release

130. On April 9, 2020, the Company put out the April 9 Press Release, in which Defendant Esfandiari stated, in relevant part:

> "Our patented technology uses one of two analyzers produced by Chembio, known as MR1 and MR2, to read the test results for both IgM and IgG antibodies from finger stick blood in 15 minutes and gives a numerical result related to the amount of antibody in the sample," … "This eliminates the individual subjectivity of results and increases the sensitivity and specificity of the test."

April 15 Press Release

131. On April 15, 2020, the Company issued the April 15 Press Release, which stated, in relevant part:

> We are very pleased with the continued progress our teams are making to address the market demands with our DPP COVID-19 serological system," stated Rick Eberly, Chembio's Chief Executive Officer. **"The flexibility of having two analyzers and a system that provides high sensitivity and specificity that is generally consistent with the performance of Chembio's other DPP platform tests as part of our offering places us in a unique position to serve a variety of markets.** Additionally, we are pleased to announce that our manufacturing team has produced and shipped our first lots of the COVID-19 Systems, and we look forward to providing further product within the US and abroad.

(Emphasis added.)

May 4, 2020 Press Releases & Investor Conference Call

May 4, 2020 Press Release 1

132. On May 4, 2020, the Company circulated the May 4 Press Release 1, in which Defendant Eberly stated, in relevant part:

> "The CE Marking is another significant accomplishment for Chembio and expands the market opportunity for our DPP COVID-19 rapid serological test meaningfully," stated Rick Eberly, Chembio's Chief Executive Officer. "We are pleased to begin commercializing and continuing to support the decentralization that is needed to address the ongoing demand for testing. **We believe our platform will add tremendous value in determining the IgM and IgG values in a variety of settings**."

(Emphasis added.)

133. The May 4 Press Release 1 continued, in pertinent part,

> The DPP COVID-19 System is a serological test and analyzer that provides numerical readings for both IgM and IgG antibody levels within 15 minutes from a simple finger stick drop of blood. Both Chembio's Micro Reader 1 and Micro Reader 2 analyzers are compatible with the test. The system is approved for use in the U.S. through the Emergency Use Authorization and in Brazil under ANVISA approval.

May 4, 2020 Press Release 2

134. On May 4, 2020, the Company published the May 4 Press Release 2, which stated, in relevant part:

> "During the first quarter, we refocused our business strategy to address the escalating need for COVID-19 diagnostic tests. In a short period of time, we developed a COVID-19 serological testing system, received FDA Emergency Use Authorization and began shipping tests to customers in the United States and Brazil in April. Our differentiated testing system offers numerical discrete detection of both IgM and IgG antibodies in approximately 15 minutes from a fingerstick. Then, in approximately 15 seconds, the DPP COVID-19 System reads the test to provide numerical results using the portable Micro Reader analyzers that are engineered and produced by our wholly owned subsidiary in Germany. **Numerical results reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many other serological tests," said Gail Page, Chembio's Executive Chair of the Board.** "We are proud to be serving the needs of clinicians and the broader healthcare community in this time of crisis."
>
> "**It has been an extremely productive first few weeks in my new role as CEO. Amid these challenging circumstances, the skill and hard work of this team has enabled a successful strategic pivot as we prioritize manufacturing and commercialization of our DPP COVID-19 System," said Richard Eberly, Chembio's Chief Executive Officer.** "Through efficient use of our resources and technical ability, we are scaling production of these tests due to the strong demand we are experiencing. **We believe the features and benefits offered by our DPP COVID-19 System will make it a preferred solution."**

(Emphasis added.)

May 4 2020 Investor Conference Call

135. The Company, led by Defendants Eberly and Page, held a conference call on that same day, May 4, 2020, (the "May 4 Conference Call") to discuss the Company's operating results for the quarter ended March 31, 2020 with investors. During the call, Defendant Eberly represented, in relevant part, that the "**accuracy of the DPP COVID-19 systems after 11 days post the onset of symptoms is 100% for total antibodies. This is based on our data that was**

submitted to and reviewed by the FDA for the EUA."[7] Defendant Page failed to correct or clarify Defendant Eberly's statements that Chembio's rapid COVID-19 antibody tests were less than 100% accurate even under the circumstances described.

May 4, 2020 Form 10-Q

136. Also on May 4, 2020, the Company filed its 1Q20 10-Q. The 1Q20 10-Q was signed by Defendants Eberly and Goldman, and contained SOX certifications signed by Defendants Eberly and Goldman attesting to the accuracy of the financial statements contained therein, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

137. The 1Q20 10-Q stated the following regarding the Company's rapid COVID-19 antibody tests:

> The DPP COVID-19 System detects antibodies in the blood that are produced by the body in response to a novel coronavirus infection. Detection of an acute infection, as determined by the level of IgM antibodies, helps determine if a patient is still infectious. As the infection progresses, the body typically begins to produce IgG antibodies. The IgG antibody levels increase, while IgM antibody levels decrease and eventually disappear. IgG antibodies remain, evidencing the earlier infection. It is not currently known how long IgG antibodies to coronavirus remain in the body.
>
> The DPP COVID-19 System offers discrete detection of IgM and IgG antibodies, with high sensitivity and specificity, from a simple fingerstick drop of blood after approximately 15 minutes of reaction time. Using our portable Micro Reader analyzer, the DPP COVID-19 System produces numerical results in approximately 15 seconds. Numerical readings of each of the IgM and IgG antibodies can assist in identifying patients who have been exposed to the novel coronavirus, even patients who exhibit mild, or no, symptoms. Numerical results reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many other serological tests. Because the reader processing requires approximately 15 seconds and is independent of the processing of tests, the DPP COVID-19 System can process more than 200 tests per hour, making it appropriate for high-volume applications.

[7] Emphasis added.

138. The 1Q20 10-Q also stated the following regarding the Company's internal controls:

> **Changes in Internal Control over Financial Reporting**. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the three months ended June 30, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

May 2020 Offering Documents

139. On May 6, 2020 and May 8, 2020, the Company filed the May 2020 Offering Documents with the SEC in connection with the May 2020 Offering. The May 6 Form 424B5 stated and the May 8 Form 424B5 reiterated, in pertinent part:

> In February 2020, we began to shift substantially all of our resources to leverage our DPP lateral flow technology to address the acute and escalating need for an accurate diagnostic test for COVID-19. By March 2020 we had developed, and begun to manufacture for commercialization, the DPP COVID-19 System, which consists of our new serological test for COVID-19 and our Micro Reader analyzer. The DPP COVID-19 System can provide discrete, numerical readings for IgM and IgG antibody levels in approximately 15 minutes from a fingerstick drop of blood. **The accuracy of the DPP COVID-19 System after 11 days post the onset of symptoms is 100% for total antibodies**.

(Emphasis added.)

140. In connection with the May 2020 Offering, the Company sold over 2.6 million shares of stock, and raised approximately $30.8 million.

May 18 Press Release

141. On May 18, 2020, the Company published the May 18 Press Release, which stated, in relevant part:

> HAUPPAUGE, N.Y., May 18, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced it has signed a multi-year, non-exclusive agreement with Thermo Fisher Scientific's healthcare channel, to distribute Chembio's DPP COVID-19 System in the United States. The DPP

> COVID-19 System is a rapid serological test and analyzer that provides numerical readings for both IgM and IgG antibody levels within 15 minutes from a finger stick drop of blood. The DPP COVID-19 System can include either Chembio's Micro Reader 1 or Micro Reader 2 analyzer.
>
> "We are pleased to announce our strategic supplier partnership with the Fisher Healthcare channel, which will significantly increase our commercial footprint by providing access to thousands of hospital and physician office moderately complex labs across the country," stated Rick Eberly, Chembio's President and Chief Executive Officer. "We have initiated a comprehensive training and marketing program for the Fisher Healthcare channel sales team, in order to expand the targeted coverage for this important segment of the market as soon as possible."

June 2 Press Release

142. On June 2, 2020, the Company disseminated a press release (the "June 2 Press Release"), which quoted the Company's newly appointed Vice President of Sales and Marketing for North America as follows, in relevant part:

> "I am very pleased to be joining Chembio and taking on this new challenge to lead the sales and marketing efforts in North America. **The company is well positioned to serve the many customer channels that can all benefit from the accuracy, speed and ease of use provided by DPP technology," said Mr. Caso.** "I look forward to working with this talented team to implement and execute commercial strategies to deliver our DPP COVID-19 program and legacy business product portfolios to a diverse customer base."

(Emphasis added.)

June 16, 2020 Proxy Statement

143. On June 16, 2020, the Company filed the 2020 Proxy Statement with the SEC. Defendants Eberly, Page, Davis, Polan, and Potthoff solicited the 2020 Proxy Statement pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.[8]

[8] Plaintiff's allegations with respect to the misleading statements in the 2020 Proxy Statement are based solely on negligence; they are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants, and they do not allege, and do not sound in, fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these allegations and related claims.

144. With respect to the Company's Code of Ethics, the 2020 Proxy Statement stated, "[w]e have a Code of Business Conduct and Ethics, or the Conduct Code, applicable to all directors, officers and employees of Chembio and its subsidiaries."

145. The 2020 Proxy Statement was false and misleading because, despite assertions to the contrary, the Code of Ethics was not followed, as evidenced by the numerous false and misleading statements alleged herein, and the Individual Defendants' failures to report violations of the Code of Ethics.

146. The 2020 Proxy Statement also failed to disclose, *inter alia*, that: (1) the Company's rapid COVID-19 antibody tests were less than 100% accurate after 11 days post the onset of symptoms; (2) the Company's rapid COVID-19 antibody tests generated a higher than expected rate of false results and higher than that reflected in the authorized labeling for the testing device; (3) the FDA had expressed grave and material performance concerns regarding the sensitivity and specificity of Chembio's rapid COVID-19 antibody test prior to revocation of the EUA on June 16, 2020; (4) accordingly, it was not reasonable to believe that the Company's rapid COVID-19 antibody tests may be effective in detecting COVID-19 resultant antibodies and, therefore, there was a material risk to public health from the poor performance and high rate of false test results; (5) the commercial viability of the Company was overstated in light of the true accuracy and efficacy of the Company's COVID-19 tests; and (6) the Company failed to maintain internal controls. As a result of the foregoing, the Individual Defendants' statements about the Company's business, operations and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

147. The statements and omissions referenced in ¶¶ 123–142 herein were materially false and misleading and failed to disclose material facts necessary to make the statements made

not false and misleading. Specifically, the Individual Defendants failed to disclose that: (1) the Company's rapid COVID-19 antibody tests were less than 100% accurate after 11 days post the onset of symptoms; (2) the Company's rapid COVID-19 antibody tests generated a higher than expected rate of false results and higher than that reflected in the authorized labeling for the testing device; (3) the FDA had expressed grave and material performance concerns regarding the sensitivity and specificity of Chembio's rapid COVID-19 antibody test prior to revocation of the EUA on June 16, 2020; (4) accordingly, it was not reasonable to believe that the Company's rapid COVID-19 antibody tests may be effective in detecting COVID-19 resultant antibodies and, therefore, there was a material risk to public health from the poor performance and high rate of false test results; (5) the commercial viability of the Company was overstated in light of the true accuracy and efficacy of the Company's COVID-19 tests; and (6) the Company failed to maintain internal controls. As a result of the foregoing, the Individual Defendants' statements about the Company's business, operations and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

The Truth Emerges

148. After markets closed on June 16, 2020, the FDA issued the June 16 FDA Press Release, disclosing that the FDA had revoked the EUA for Chembio's COVID-19 antibody test. The FDA also sent the Company a letter dated June 16, 2020 notifying the Company of its revocation of the EUA. The June 16 FDA Press Release stated the following, in relevant part:

> Today, the U.S. Food and Drug Administration revoked the emergency use authorization (EUA) of the Chembio Diagnostic System, Inc. (Chembio) DPP COVID-19 IgM/IgG System, a SARS-CoV-2 antibody test, due to performance concerns with the accuracy of the test. Antibody tests, a type of serological test, can help provide information on a person's and population's exposure to COVID19.
> …

> Data submitted by Chembio as well as an independent evaluation of the Chembio test at NCI showed that this test generates a higher than expected rate of false results and higher than that reflected in the authorized labeling for the device. Under the current circumstances of the public health emergency, it is not reasonable to believe that the test may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the test outweigh the known and potential risks of the test, including the high rate of false results. Moreover, the risk to public health from the false test results makes EUA revocation appropriate to protect the public health or safety. As such, the FDA decided to revoke the emergency use authorization of the Chembio test, and this test may not be distributed.

149. On June 17, 2020, the Company filed the June 17 8-K, which acknowledged receipt of the FDA's June 16, 2020 letter. The June 17 8-K stated the following, in relevant part:

> On June 16, 2020, we received a letter from the U.S. Food and Drug Administration, or FDA, notifying us that the FDA was revoking the Emergency Use Authorization, or EUA, granted in April 2020 with respect to our DPP COVID-19 System, which consists of our serological test for COVID-19 and one of our Micro Reader analyzers. As a result of this decision by the FDA, we may no longer distribute the DPP COVID-19 System.
>
> The DPP COVID-19 System was one of the first antibody tests authorized by the FDA during the COVID-19 public health emergency. Based on the information that we submitted to the FDA at the time of authorization, the FDA concluded that our test system met the applicable "may be effective" standard for an EUA.
>
> In its letter of June 16, 2020, the FDA stated that it had decided to revoke the EUA for the DPP COVID-19 System due to performance concerns regarding the sensitivity and specificity of our test system. According to the FDA, an independent evaluation of our test system by the National Institutes of Health's National Cancer Institute, as well as other independent evaluations, showed (a) our test system generated a higher rate of false results than expected under our initial EUA request and our authorized labeling and (b) it is not reasonable to believe that our test system may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of our test system outweigh its known and potential risks.
>
> We intend to continue working with the FDA with respect to the modification of the DPP COVID-19 System and of the revocation of the EUA for our test system.

150. On this news, the price of the Company's stock plunged from $9.93 per share at the close of trading on June 16, 2020, to $3.89 per share at the close of trading on June 17, 2020, representing a stunning loss in value of more than 60%—the Company's largest stock drop in 18

years—on a massive trading volume of nearly 27 million shares—almost four times the average daily, three-month volume.[15]

151. Also on June 17, 2020, Bloomberg published an article titled "FDA Reversal on Chembio Antibody Test Sends Stock Down 63%" (the "Bloomberg Article")[16] reporting that Chembio's stock "lost more than half its value on [June 17, 2020] after U.S. regulators revoked its right to sell a test for COVID-19 antibodies over accuracy concerns." Moreover, the Bloomberg Article noted that Canaccord analyst, Max Masucci, slashed his share price target on Chembio's stock from $22 to $7 and joined four other analysts in downgrading their outlook of the Company's valuation.

DAMAGES TO CHEMBIO

152. As a direct and proximate result of the Individual Defendants' conduct, Chembio will lose and expend many millions of dollars.

153. Such expenditures include, but are not limited to, legal fees associated with the Securities Class Actions filed against the Company, its President and CEO, its former interim CEO, and its CFO, and any internal investigations, and amounts paid to outside lawyers, accountants, and investigators in connection thereto.

154. These expenditures also include, but are not limited to, compensation and benefits paid to the Individual Defendants who breached their fiduciary duties to the Company.

155. As a direct and proximate result of the Individual Defendants' conduct, Chembio has also suffered and will continue to suffer a loss of reputation and goodwill, and a "liar's discount" that will plague the Company's stock in the future due to the Company's and their

[15] For example, approximately 1,438,600 shares of the Company's stock were traded just one day prior, on June 16, 2020.

[16] https://www.bloombergquint.com/business/fda-reversal-on-chembio-test-sounds-an-alarm-for-canaccord (last visited September 10, 2020).

misrepresentations and the Individual Defendants' breaches of fiduciary duties and unjust enrichment.

DERIVATIVE ALLEGATIONS

156. Plaintiff brings this action derivatively and for the benefit of Chembio to redress injuries suffered, and to be suffered, as a result of the Individual Defendants' breaches of their fiduciary duties as directors and/or officers of Chembio, unjust enrichment, and violations of the Exchange Act, as well as the aiding and abetting thereof.

157. Chembio is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

158. Plaintiff is, and has been at all relevant times, a shareholder of Chembio. Plaintiff will adequately and fairly represent the interests of Chembio in enforcing and prosecuting its rights, and, to that end, has retained competent counsel, experienced in derivative litigation, to enforce and prosecute this action.

DEMAND FUTILITY ALLEGATIONS

159. Plaintiff incorporates by reference and re-alleges each and every allegation stated above as if fully set forth herein.

160. A pre-suit demand on the Board of Chembio is futile and, therefore, excused. At the time of filing of this action, the Board consists of the following four individuals: Defendants Eberly, Davis, Polan, and Potthoff, (the "Directors"). Plaintiff needs only to allege demand futility as to two of the four Directors who are on the Board at the time this action is commenced.

161. Demand is excused as to all of the Directors because each one of them faces, individually and collectively, a substantial likelihood of liability as a result of the scheme they engaged in knowingly or recklessly to cause the Company to make false and misleading statements

and omissions of material facts, which renders them unable to impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme.

162. In complete abdication of their fiduciary duties, the Directors either knowingly or recklessly participated in making and/or causing the Company to make the materially false and misleading statements alleged herein. The fraudulent scheme was intended to make the Company appear more profitable and attractive to investors. As a result of the foregoing, the Directors breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

163. The Directors knew of the falsity of the misleading statements at the time they were made. The development and commercialization of COVID-19 tests is currently the core operation of Chembio. The accuracy of the COVID-19 tests is highly material to the Company's core operations, which is reflected in the Company' stock price and made clear by the Company's March 12 Press Release 1, March 12 Press Release 2, March 12 Press Release 3, March 31 Press Release, April 9 Press Release, April 15 Press Release, May 4 Press Release 1, May 4 Press Release 2, May 18 Press Release, June 2 Press Release, May 2020 Offering Documents, March 12 Conference Call and May 4 Conference Call, and the Company's recent filings with the SEC, including, but not limited to, the Company's 2019 10-K, 1Q20 10-Q, 2Q20 10-K, and June 17 8-K.

164. As Board members of Chembio, charged with overseeing the Company's affairs, the Directors all must have had knowledge or information pertaining to the Company's core operations and the material events giving rise to these claims. Specifically, as members of Chembio's Board, the Directors must have been aware of the material facts surrounding the accuracy of the COVID-19 tests described herein, including the revelations brought to light by

third-parties, including, but not limited to, the FDA, and Bloomberg, and acknowledged by the Company's CEO, Defendant Eberly, and CFO, Defendant Goldman.

165. This inference of actual knowledge of the falsity of the misleading statements and omissions at issue is further supported by the sophistication of the Company's Directors, which is touted in Chembio filings with the SEC, as referenced above.

166. Therefore, the Directors each knew of the falsity of the statements and misleading omissions detailed herein at the time such statements were made, and further failed to exercise or recklessly disregarded their duty of oversight to stop or correct such misleading statements and omissions.

167. Additional reasons that demand on Defendant Eberly is futile follow. Defendant Eberly has served as the Company's President and CEO since March 16, 2020. Thus, as the Company admits, he is a non-independent director. The Company provides Defendant Eberly with his principal occupation, and, according to the Eberly Employment Agreement, he receives handsome compensation, including at least $400,000 in base salary in 2020 for his services. Defendant Eberly was ultimately responsible for all of the false and misleading statements and omissions that were made, including those contained in the Company's SEC filings and press releases referenced herein. As the Company's highest officer and as a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Eberly signed, and thus personally made the false and misleading statements in the 1Q20 10-Q referenced herein, in addition to falsely representing that the Company's COVID-19 antibody test was 100% accurate after 11 days post the onset of symptoms in the

Company's May 4 Conference Call with investors and press releases. Furthermore, Defendant Eberly is a defendant in the Securities Class Actions. For these reasons, Defendant Eberly breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

168. Additional reasons that demand on Defendant Davis is futile follow. Defendant Davis serves as the Company's Chairperson of the Board, and has served as a director since 2007. Previously, she served as the Executive Chairperson of the Board from March 2014 until April 23, 2020. Defendant Davis also serves as the Chair of the Company's Nominating and Corporate Governance Committee, and as a member of the Audit Committee and Compensation Committee. Defendant Davis has received and continues to receive compensation for her role as a director as described above. As a trusted Company director, she conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded her duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded her duties to protect corporate assets. Furthermore, Defendant Davis signed, and thus personally made the false and misleading statements in the 2019 10-K. For these reasons, Defendant Davis breached her fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon her is futile and, therefore, excused.

169. Additional reasons that demand on Defendant Polan is futile follow. Defendant Polan has served as a Company director since August 2018. She also serves as the Chair of the Company's Compensation Committee and as a member of the Audit Committee and Nominating and Corporate Governance Committee. Defendant Polan has received and continues to receive compensation for her role as a director as described above. As a trusted Company director, she conducted little, if any, oversight of the scheme to cause the Company to make false and

misleading statements, consciously disregarded her duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded her duties to protect corporate assets. Furthermore, Defendant Polan signed, and thus personally made the false and misleading statements in the 2019 10-K. For these reasons, Defendant Polan breached her fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon her is futile and, therefore, excused.

170. Additional reasons that demand on Defendant Potthoff is futile follow. Defendant Potthoff has served as a Company director since May 2018. He also serves as the Chair of the Company's Audit Committee, and as a member of the Compensation Committee and Nominating and Corporate Governance Committee. Defendant Potthoff has received and continues to receive compensation for his role as a director as described above. As a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Furthermore, Defendant Potthoff signed, and thus personally made the false and misleading statements in the 2019 10-K. For these reasons, Defendant Potthoff breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

171. Additional reasons that demand on the Board is futile follow.

172. Defendants Davis, Polan, and Potthoff (the "Audit Committee Defendants") served on the Company's Audit Committee during the Relevant Period. Pursuant to the Company's Audit Committee Charter, the Audit Committee Defendants were responsible for overseeing, *inter alia*, the Company's the integrity of the Company's financial statements, the Company's compliance

with legal and regulatory requirements, the Company's financial reporting process, and the Company's internal controls over financial reporting. The Audit Committee Defendants failed to ensure the integrity of the Company's financial statements, as they are charged to do under the Audit Committee Charter, allowing the Company to file false and misleading financial statements with the SEC and to fail to maintain internal controls. Thus, the Audit Committee Defendants breached their fiduciary duties, are not disinterested, and demand is excused as to them.

173. The Directors have longstanding business and personal relationships with each other and the Individual Defendants that preclude them from acting independently and in the best interests of the Company and the shareholders. These conflicts of interest precluded the Directors from adequately monitoring the Company's operations and internal controls and calling into question the Individual Defendants' conduct. Thus, demand upon the Directors would be futile.

174. In violation of the Code of Ethics, the Directors conducted little, if any, oversight of the Company's internal controls over public reporting and of the Company's involvement in the Individual Defendants' scheme to issue materially false and misleading statements to the public and to facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, and violations of the Exchange Act. In violation of the Code of Ethics, the Directors failed to comply with the law. Thus, the Directors face a substantial likelihood of liability and demand is futile as to them.

175. Chembio has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Directors have not filed any lawsuits against themselves or others who were responsible for that wrongful conduct to attempt to recover for Chembio any part of the damages Chembio suffered and will continue to suffer thereby. Thus, any demand upon the Directors would be futile.

176. The Individual Defendants' conduct described herein and summarized above could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the Directors can claim exculpation from their violations of duty pursuant to the Company's charter (to the extent such a provision exists). As a majority of the Directors face a substantial likelihood of liability, they are self-interested in the transactions challenged herein and cannot be presumed to be capable of exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.

177. The acts complained of herein constitute violations of fiduciary duties owed by Chembio's officers and directors, and these acts are incapable of ratification.

178. The Directors may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate funds, i.e., monies belonging to the stockholders of Chembio. If there is a directors' and officers' liability insurance policy covering the Directors, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Directors, known as, *inter alia*, the "insured-versus-insured exclusion." As a result, if the Directors were to sue themselves or certain of the officers of Chembio, there would be no directors' and officers' insurance protection. Accordingly, the Directors cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Directors is futile and, therefore, excused.

179. If there is no directors' and officers' liability insurance, then the Directors will not cause Chembio to sue the Individual Defendants named herein, because, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event, as well.

180. Thus, for all of the reasons set forth above, all of the Directors, and, if not all of them, at least two of the Directors cannot consider a demand with disinterestedness and independence. Consequently, a demand upon the Board is excused as futile.

FIRST CLAIM

Against Individual Defendants for Violations of Section 14(a) of the Exchange Act

181. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

182. The Section 14(a) Exchange Act claims alleged herein are based solely on negligence. They are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants. The Section 14(a) claims alleged herein do not allege and do not sound in fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these nonfraud claims.

183. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that "[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any

proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78l]."

184. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain "any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." 17 C.F.R. §240.14a-9.

185. Under the direction and watch of the Directors, the 2020 Proxy Statement failed to disclose, *inter alia*, that: (1) the Company's rapid COVID-19 antibody tests were less than 100% accurate after 11 days post the onset of symptoms; (2) the Company's rapid COVID-19 antibody tests generated a higher than expected rate of false results and higher than that reflected in the authorized labeling for the testing device; (3) the FDA had expressed grave and material performance concerns regarding the sensitivity and specificity of Chembio's rapid COVID-19 antibody test prior to revocation of the EUA on June 16, 2020; (4) accordingly, it was not reasonable to believe that the Company's rapid COVID-19 antibody tests may be effective in detecting COVID-19 resultant antibodies and, therefore, there was a material risk to public health from the poor performance and high rate of false test results; (5) the commercial viability of the Company was overstated in light of the true accuracy and efficacy of the Company's COVID-19 tests; and (6) the Company failed to maintain internal controls. As a result of the foregoing, the Individual Defendants' statements about the Company's business, operations and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

186. The Individual Defendants also caused the Proxy Statement to be false and misleading with regard to executive compensation in that they purported to employ "pay-for-

performance" elements, while failing to disclose that the Company's financial prospects were misrepresented as a result of false and misleading statements, causing the Company's share price to be artificially inflated and allowing the Individual Defendants to wrongfully benefit from the fraud alleged herein.

187. Moreover, the 2020 Proxy Statement was false and misleading when it discussed the Company's adherence to specific governance policies and procedures, including the Code of Ethics, due to the Individual Defendants' failures to abide by them and their engagement in the scheme to issue false and misleading statements and omissions of material fact.

188. In the exercise of reasonable care, the Individual Defendants should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the 2020 Proxy Statement were materially false and misleading. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for shareholder determination in the 2020 Proxy Statement, including but not limited to: (1) election of directors; (2) approval of a proposal to change the Company's state of incorporation from Nevada to Delaware (the "Reincorporation Proposal"); (3) ratification of the Company's independent auditor; and (4) an advisory vote on 2019 executive compensation.

189. The false and misleading elements of the 2020 Proxy Statement led to the rejection of the Reincorporation Proposal, and to the re-election of Defendants Eberly, Page, Davis, Polan, and Potthoff, which allowed them to continue breaching their fiduciary duties to Chembio.

190. The Company was damaged as a result of the Individual Defendants' material misrepresentations and omissions in the 2020 Proxy Statement.

191. Plaintiff on behalf of Chembio has no adequate remedy at law.

SECOND CLAIM

Against the Individual Defendants for Breach of Fiduciary Duties

192. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

193. Each Individual Defendant owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Chembio's business and affairs.

194. Each of the Individual Defendants violated and breached his or her fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

195. The Individual Defendants' conduct set forth herein was due to their intentional or reckless breach of the fiduciary duties they owed to the Company, as alleged herein. The Individual Defendants intentionally or recklessly breached or disregarded their fiduciary duties to protect the rights and interests of Chembio.

196. In breach of their fiduciary duties owed to Chembio, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (1) the Company's rapid COVID-19 antibody tests were less than 100% accurate after 11 days post the onset of symptoms; (2) the Company's rapid COVID-19 antibody tests generated a higher than expected rate of false results and higher than that reflected in the authorized labeling for the testing device; (3) the FDA had expressed grave and material performance concerns regarding the sensitivity and specificity of Chembio's rapid COVID-19 antibody test prior to revocation of the EUA on June 16, 2020; (4) accordingly, it was not reasonable to believe that the Company's rapid COVID-19 antibody tests may be effective in detecting COVID-19 resultant antibodies and, therefore, there was a material risk to public health from the poor performance and high rate of false test results; (5) the

commercial viability of the Company was overstated in light of the true accuracy and efficacy of the Company's COVID-19 tests; and (6) the Company failed to maintain internal controls. As a result of the foregoing, the Individual Defendants' statements about the Company's business, operations and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

197. The Individual Defendants also failed to correct and caused the Company to fail to correct the false and misleading statements and omissions of material fact, rendering them personally liable to the Company for breaching their fiduciary duties.

198. In further breach of their fiduciary duties, the Individual Defendants failed to maintain an adequate system of oversight, disclosure controls and procedures, and internal controls.

199. The Individual Defendants had actual or constructive knowledge that the Company issued materially false and misleading statements, and they failed to correct the Company's public statements and representations. The Individual Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth, in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and omissions were committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of Chembio's securities.

200. The Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly engage in the fraudulent schemes set forth herein and to fail to maintain internal controls. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent schemes set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to

improperly engage in the fraudulent schemes and to fail to maintain adequate internal controls, even though such facts were available to them. Such improper conduct was committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of Chembio's securities.

201. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

202. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Chembio has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

203. Plaintiff on behalf of Chembio has no adequate remedy at law.

THIRD CLAIM

Against the Individual Defendants for Unjust Enrichment

204. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

205. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Chembio.

206. The Individual Defendants either benefitted financially from the improper conduct, or received profits, bonuses, stock options, or similar compensation from Chembio that was tied to the performance or artificially inflated valuation of Chembio, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct.

207. Plaintiff, as a shareholder and a representative of Chembio, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits, including from insider transactions, benefits, and other compensation, including any performance-based or

valuation-based compensation, obtained by the Individual Defendants due to their wrongful conduct and breach of their fiduciary and contractual duties.

208. Plaintiff on behalf of Chembio has no adequate remedy at law.

PRAYER FOR RELIEF

FOR THESE REASONS, Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows:

(a) Declaring that Plaintiff may maintain this action on behalf of Chembio, and that Plaintiff is an adequate representative of the Company;

(b) Declaring that the Individual Defendants have breached or aided and abetted the breach of their fiduciary duties to Chembio;

(c) Determining and awarding to Chembio the damages sustained by it as a result of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre-judgment and post-judgment interest thereon;

(d) Directing Chembio and the Individual Defendants to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Chembio and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote the following resolutions for amendments to the Company's Bylaws or Articles of Incorporation and the following actions as may be necessary to ensure proper corporate governance policies:

1. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the board;

2. a provision to permit the shareholders of Chembio to nominate at least two candidates for election to the Board; and

3. a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations.

(e) Awarding Chembio restitution from Individual Defendants, and each of them;

(f) Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and

(g) Granting such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: September 11, 2020

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

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Counsel for Plaintiff

VERIFICATION

I, Karen Wong am a plaintiff in the within action. I have reviewed the allegations made in this shareholder derivative complaint, know the contents thereof, and authorize its filing. To those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 9/10/2020 day of _____, 2020.

DocuSigned by:
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Karen Wong